Diagnostic Procedure: TB Test

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Diagnostic Procedure: The Tuberculin Test
General Information

The tuberculin skin test is the traditional method of diagnosing infection with *Mycobacterium tuberculosis.* While the test is not completely sensitive and specific, no better diagnostic test has been developed. An accurate interpretation of skin test results requires a knowledge of the antigen used, i.e., tuberculin, the immunologic basis for the reaction to this antigen, the techniques of administering and reading the test, and the results of epidemiologic and clinical experiences with the test.

The tuberculin skin test is based on the fact the infection with M. tuberculosis procedures sensitivity to certain components of this organism (antigens), which are contained in culture extracts called "tuberculins." Two preparations of tuberculin are currently licensed for use in this country: Old tuberculin (OT) and purified protein derivative (PPD). The OT is available only in multiple puncture devices, which are considered to lack both sensitivity and specificity and are not recommended for public health use.

PPD tuberculin is available for intradermal injection by the Mantoux technique and for percutaneous multi puncture devices. Only the procedure for the Mantoux technique is addressed in this manual due to the unacceptable levels of both sensitivity and specificity of the multi puncture devices.

PPD is available in various strengths, containing one (1) tuberculin unit (TU), 5 TU, and 250 TU. Only 5 TU is routinely used in public health and is the only strength PPD addressed in this manual.

PPD is light and heat sensitive and when not being used should be protected from light and stored in a refrigerator at 35-46° Fahrenheit. While in use in the field or being transported from the health department to another site, it should be in a cooler with dry or regular ice, but protected from freezing.

PPD should never be transferred from one vial to another. Although a detergent (Tween 80) has been added to the tuberculin, it can adhere to the material of the vial or syringe, thereby compromising the strength of the PPD.

Diagnostic Procedure: The Tuberculin Test
General information
Immunologic Basis for the Tuberculin Reaction

The reaction to intradermally injected tuberculin is the classic example of a delayed (cellular) hypersensitivity reaction. Characteristically, delayed hypersensitivity reactions to tuberculin begin at 5 to 16 hours, are maximal at 48 to 72 hours, and subside over a period of days. In a few persons, those who are elderly or those being tested for the first time, reactions may gradually wane over the years and the "booster phenomenon" may occur (see page 32 of *Core Curriculum*). Immediate hypersensitivity reactions to tuberculin or constitutes of the diluent can also occur. However, these reactions begin shortly after injection, disappear by 24 hours, and are not likely to be confused with delayed hypersensitivity reactions.

Some persons may develop a positive reaction after seventy-two (72) hours. These later reactions generally develop within a week. These reactions should be considered positive even if they do not peak within seventy-two (72) hours (see page 29 of the *Core Curriculum).*

Diagnostic Procedure: The Tuberculin Test
Multiple-Puncture (Tine) Test

POLICY: Multiple puncture (tine) tuberculin skin tests are not appropriate for use in the diagnosis of tuberculosis infection or disease.

PURPOSE: To discourage the use of multiple-puncture tuberculin skin test in Missouri.

PROCEDURE: As multiple-puncture (tine) test are not appropriate for use in the diagnosis of tuberculosis infection or disease, multiple-puncture test should not be used. If multiple-puncture test has been used, unless the reaction is vesicular (blistered), **it must be retested with the Mantoux method**. If the multiple-puncture test reaction is vesicular, it is considered "positive," but there is no basis on which to appropriately classify the reaction (see page 29 of the *Core Curriculum*).

Diagnostic Procedure: The Tuberculin Test
Administration of the Mantoux Tuberculin Skin test

POLICY: Tuberculin skin tests will be administered as outlined in the Procedure section below.

PURPOSE: To provide standardization of administration of tuberculin skin tests in Missouri.

PROCEDURE: The Mantoux method is the standard for all tuberculin tests in Missouri. There must be a physician's order to perform tuberculin tests at local public health agency (LPHA).

The Mantoux method involves the intradermal injection of five (5) Tuberculin Units (TU) of Purified Protein Derivative (PPD). The usual injection site is the volar or dorsal surface of the arm, however, other sites such as the scapular area of the back, can be used.

Equipment and Supplies:

- Health care provider's individual or standing order for administering the PPD
- Sterile 1 ml. tuberculin syringe with 27 gauge blunt beveled 1/4 - 1/2 inch needle.
- Alcohol pads.
- 5TU PPD - Properly stored at 2-8° C/35-46° F (refrigerator temperature) and handled to avoid unnecessary exposure to light (return to refrigerator or cooler as soon as possible after use).
- Cotton balls.
- Approved infectious waste/used sharps disposal containers.
- Ruler with mm indicators.
- Documentation of history, signature for request to be tested, antigen, strength, dose, site, date, name of person administering the test, etc as needed. A TBC-4 may be used for this purpose.

- **If the person to be tuberculin skin tested is <18 years of age, the parent or**

guardian must sign the request for testing.

- Emergency kit and standing orders for use should an anaphylactic reaction occur (extremely rare).

Before administering the PPD:

Ascertain if the test is appropriate: review available medical records and/or question the individual regarding previous history of tuberculosis (TB), TB treatment, or previous history of positive PPD with or without isoniazid (INH) infection treatment. Sample questions include:

1. Have you ever been told that you have TB? If so, when, where, and by whom?

   What medications were used in treatment and how long did you take them? (If applicable, obtain a signed release of information to secure data or pursue data by phone.)

2. Have you ever been tested for TB? If so, why was the test done, when, where, and by whom?

3. Was the test applied with a needle under the surface of your skin with a bubble appearing or was a pronged device used (tine)?

4. What sort of reaction did you have at the site two or three days later, such as a bump or multiple bumps, redness, swelling, blistering? Did you return to have the test read two or three days later? If so, what were you told about the reaction? (Answers might be the mm reading, "positive" or "negative"). If the answer is anything but "negative" or "less than 10 mm" or "there was nothing there," continue on with the next question.

5. Did you have a chest x-ray at the time you had your previous skin test? If so, what were you told as to why it was being done, by whom, and where did you go to get the x-ray? What were you told about the x-ray results? Were you put on any medication(s) that you had to take for a long time (6-12 months or more) for TB? What was (were) the name of the medication(s)? Where, when, and by whom were these prescribed? How long did you take them and how would you describe how well you took them? (If the individual doesn't know the name[s] of the drug[s], but describes the medication as one or three tablets a day for 6-12 months, treatment may have been INH infection treatment. If the medication is described as two or more different medications taken for 6-12 months or more, treatment may have been for TB disease. If possible, verify treatment with the provider indicated by the individual.) If you determine in your questioning that the individual was skin tested with a multiple-puncture (tine) with a reaction other than blistering and did not receive infection treatment for at least 6 months, then a Mantoux test should be administered.

If you determine in your questioning that the individual has had a measurable induration to a Mantoux skin test that was 10 or more mm, then **DO NOT** repeat the skin test. Infection with *M. tuberculosis* has already been identified and does not need to be confirmed.

If you determine in your questioning that there is no significant previous skin test history, or the previous reaction needs to be confirmed in millimeters, prepare to administer the Mantoux tuberculin test. **Repeated testing of uninfected persons does not sensitize them to tuberculin, therefore frequent tuberculin skin tests, if appropriate, are NOT CONTRAINDICATED.**

Assess factors such as the person's age and skin condition. Assess the level of understanding that will determine the level of eductional material that is given prior to and following the skin test.

Obtain the person's signature (or parent/guardian's signature) for the tuberculin skin test. The TBC-4 may be used. (See Section 8.6.)

Procedure for Administration of Tuberculin Skin Test

1. Explain the procedure to the individual: how the test is administered, the importance of returning for reading the skin test in 48-72 hours, what the skin test reaction may mean. Provide educational material according to the person's level of understanding.

2. Remove the vial of 5TU PPD from the refrigerator (or cooler if in the field). **DO NOT use if the expiration date has passed.**

   If opening a new vial of PPD, write the current date on the label. ANY UNUSED PPD MUST BE DISCARDED ONE (1) MONTH AFTER OPENING.

3. Verify that the PPD is clear, colorless, and that there are no foreign objects. Discard any questionable PPD.

4. Remove the syringe with needle from sterile packaging. Ensure that the needle is securely attached to the syringe to prevent accidental separation during injection.

5. Remove the flip top from the vial of PPD. Wipe the top of the vial with an alcohol pad using a rotary motion. **Each new vial of PPD should be labeled with the date it is opened, and NOT used after thirty (30) days have elapsed since it was first opened.**

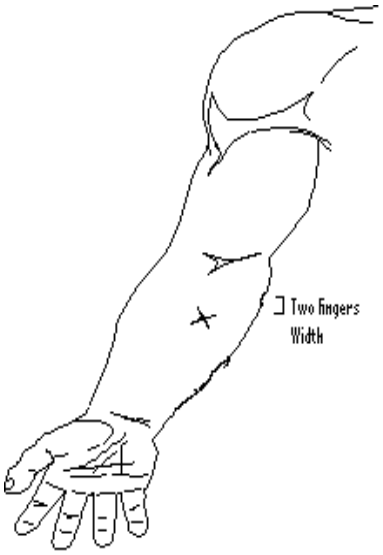
6. Remove the needle cap and draw approximately 0.2-0.3 ml. of air into the syringe, being careful to handle the plunger only by its uppermost end to avoid contaminating the interior of the barrel.

7. Puncture the vial stopper in the center with the needle and inject the air.

8. Invert the vial, support with fingers, and hold at eye level while slowly withdrawing 0.1 ml. of PPD. Try to avoid drawing air into the syringe.

9. Withdraw the needle from the vial and recap, taking care not to contaminate the needle. Since PPD is light and heat sensitive, it should be returned to the refrigerator or cooler when not in use. **SKIN TESTS SHOULD BE GIVEN IMMEDIATELY AFTER THE SYRINGE HAS BEEN FILLED** to avoid PPD adhering to the inside of the barrel of the syringe.

10. Prepare the injection site. The volar or dorsalsurface of the forearm is preferred, however, other areas such as the scapular area of the back may be used. The site should be 2 finger widths below the bend of the arm in an area that is free from hair, subsurface blood vessels, and blemishes. (see diagram.) This area is free of underlying structures that may complicate reading induration. The use of gloves during the administration of the intradermal injection is a matter of personal preference and/or agency policy, rather than being a standard recommendation of Centers for Disease Control and Prevention and the Missouri Department of Health & Senior Services. Technical skill with this procedure usually prevents the possible transmission of any blood-borne pathogens.



11. Cleanse the injection site with an alcohol pad using a circular motion from the center of the site outward. Allow the site to air dry.

12. Uncap the syringe. With your opposite hand, pull the skin of the site taut either by grasping the underside of the arm and exerting pressure downward or by using the thumb and pulling the skin of the forearm toward the wrist.

13. Position the needle at a 15° angle (almost flat) to the skin, with the bevel up. Puncture the skin and insert the needle tip until the bevel is no longer visible, taking care not to go too deep.

14. Inject the PPD. A discrete, pale elevation of the skin, i.e., a wheal 6-10 mm in diameter should be produced when 0.1 ml. is injected properly. Withdraw the needle from the skin and discard the uncapped needle and syringe in an approved infectious waste/used sharps container. **DO NOT MASSAGE OR APPLY PRESSURE TO THE SITE.** A drop of

blood may form at the injection site. If this occurs, lightly stroke the site with a dry cotton ball.

15. If a wheal, as described above, does not form, the injection has not been administered correctly. In such case, choose another site at least 2 inches away from the previous site and administer another test, following the above procedure. **THERE IS NO NEED TO WAIT TO ADMINISTER THIS TEST--IT CAN BE ADMINISTERED IMMEDIATELY.**

16. Instruct the person to not apply pressure to, scratch, or apply any non-prescribed medication or dressing to the injection site. A Band-aid is not necessary, but may be loosely applied if the person requests it. **Bathing does NOT interfere with the Mantoux tuberculin skin test.**

17. Schedule an appointment for reading the test 48-72 hours later. If two-step testing is being performed, it is acceptable to schedule reading one week after the test administered.

Additional Information: Untoward reactions to PPD are very uncommon and usually represent a high degree of sensitivity to the tuberculin. A few exceptionally sensitive persons may respond to tuberculin testing with vesicular or ulcerating local reactions, lymphangitis, regional adenopathy and/or fever. Local reactions of this severity should be covered with a dry sterile dressing to prevent secondary infection. Topical therapy may be prescribed.

Anaphylactic reactions immediately following administration of PPD are extremely rare. However, as a precautionary measure, **emergency supplies and orders must be available whenever a tuberculin skin test is administered.**

Diagnostic procedure: The Tuberculin Test
Reading the Mantoux Tuberculin Test

POLICY: Tuberculin skin tests will be read as outlined in the procedure section below.

PURPOSE: To provide standardization of reading of tuberculin skin test in Missouri.

PROCEDURE: Reading of the Mantoux tuberculin skin test must be done with good light, and with the arm slightly flexed at the elbow. The presence or absence of induration (an area of hardened tissue--*Taber's Cyclopedic Medical Dictionary*) is the basis of the reading of the test. Induration is determined by visual inspection from the side view against the light and with direct light to observe any elevation of the site, and by palpation of the site by light stroking of the site with the fingertips to feel the presence or absence of induration. **Erythema (redness caused by capillary congestion) is disregarded and is NOT read or recorded.**

If induration is present, the edges must be carefully noted, and measured using a flexible ruler marked in millimeters (mm.). The measurement is across the largest diameter of the induration. The actual measurement in mm. is recorded, NOT "positive" or "negative." **If there is no induration, the reading is recorded as "0 mm".**

If vesicles or blisters have formed from the Mantoux tuberculin skin test, this fact should also be noted.

Diagnostic Procedure: The Tuberculin Test
Interpretation of the Mantoux Tuberculin Test

POLICY: Tuberculin skin tests will be interpreted as outlined in the procedure section below.

PURPOSE: To provide standardization of interpretation of tuberculin skin test results in Missouri.

PROCEDURE: The following classifications are reasonable parameters to generally classify tuberculin skin test reactions in Missouri. Both classifications refer **only** to tests using Purified Protein Derivative (PPD) in the 5 tuberculin unit (5TU) strength administered by the Mantoux (intradermal) method as described in Diagnosis--Tuberculin Skin Test--Administration.

A. A reaction of **five (5) or more millimeters** of induration is classified as positive for the following:

1. Close contacts of persons with infectious tuberculosis.
2. Immunosuppressed persons, including those with HIV infection and persons on immunosuppressive therapy.
3. Persons with abnormal chest x-rays that show fibrotic lesions likely to represent old healed, but untreated or inadequately treated, tuberculosis disease.

B. A reaction of **ten (10) or more millimeters** of induration is classified as positive for the following:

1. Foreign-born persons from countries with a high prevalence of tuberculosis (Southeast Asia, Africa, Eastern Europe, Central and South America, the Caribbean, and the Pacific Islands) **regardless of a history of vaccination with BCG.**
2. Injecting drug users and alcoholics.
3. Residents, employees, and volunteers of correctional facilities, long-term care facilities, mental health facilities, and drug treatment centers.
4. Employees, volunteers, students and physicians of health care facilities.
5. Homeless individuals and those who work in homeless shelters.
6. Persons with diabetes mellitus, post-gastrectomy, silicosis, prolonged corticosteroid use (e.g., Prednisone 20 mg or greater for more than three (3) weeks), or those who are 10 percent or more below ideal body weight.
7. Persons who teach or provide care to young children.
8. Children under 15 years of age.

For all persons who do not fit into the above situations it may not be appropriate or effective to apply the tuberculin skin test. **It is important to remember that a tuberculin skin test reaction of less than the above parameters does not necessarily rule out tuberculosis disease.** Persons may have impaired immune systems and not be able to react appropriately to the tuberculin. Every year approximately 30 percent of Missouri's confirmed cases with known PPD status are PPD negative.

C. A tuberculin reaction of **15 or more millimeters** of induration is classified as positive in persons with no known risk factors for TB. (For all persons who do not fit in to the above situations it may not be appropriate or effective to apply the tuberculin skin test.)

Diagnostic Procedure: The Tuberculin Test
Recording Results of the Tuberculin Skin Test

POLICY: The results of tuberculin skin tests will be recorded in a standard format throughout the state of Missouri.

PURPOSE: To standardize the recording of tuberculin skin tests, thereby ensuring that the results are understood by all health care providers.

PROCEDURE: The size of the reaction (induration only) to the Mantoux PPD tuberculin skin test will be recorded in mm only, including recording "0" mm when there is no induration. All positive reactions are to be reported to the local public health agency (LPHA). It is suggested that LPHAs report tuberculosis infection on the TBC-4 and forward a copy to the state health department.

Diagnostic Procedure: The Tuberculin Test
Reporting of Positive Tuberculin Skin Test

POLICY: Tuberculin skin tests reactions indicating tuberculosis infection/disease are reported to the Missouri Department of Health in accordance with *19 CSR20-20.020* (See Appendix III).

PURPOSE: To provide data regarding the incidence of tuberculosis infection/disease in Missouri.

PROCEDURE: **Health Care Providers** (including general hospital outpatient departments, infirmaries of state and local correctional and mental institutions, federal facilities, as well as private health care providers in the community) are required by law to report tuberculosis infection and disease to the Missouri Department of Health within twenty-four (24) hours of suspected or confirmed TB.

This report is submitted in writing to the LPHA. We suggest using Form TBC-4 to report infection. (see Section 9.3).

LPHAs are requested to submit reports of tuberculosis infection. The TBC-4 is suggested for this purpose because it includes additional information important for tuberculosis surveillance, e.g., risk factors, reason for administering the tuberculin skin test. This form may also be used by the LPHA in follow-up and management of the person placed on infection treatment for tuberculosis infection. It can also be used as the only required medical record for persons being treated with infection treatment, provided that there are no complications or untoward events.

Diagnostic Procedure: The Tuberculin Test
Follow-up of Tuberculin Test Reactions

POLICY: Results of tuberculin skin test reactions will be followed as outlined in the Procedure section below.

PURPOSE: To ensure appropriate follow-up on all persons who have had tuberculin skin tests.

PROCEDURE: Follow-up medical evaluation, including chest x-rays, is imperative for all persons with a skin test reading classified as positive. Additional tuberculin skin testing and/or anergy testing may be appropriate for persons with a skin test reading classified as negative (see Chapter 6 of *Core Curriculum*).

For persons with a skin test reading classified as **positive** (see Section 4.0):

- A chest x-ray as soon as possible.
- A complete medical evaluation, including symptoms of tuberculosis, prior medical history, family history.
- Bacteriologic examinations of sputum or other body fluids for the presence of *M. tuberculosis* (if indicated because of abnormal chest x-ray or symptoms of possible TB disease).
- If current tuberculosis disease has been ruled out by the above procedures and there is no history of prior treatment for either tuberculosis disease or infection, consideration of infection treatment to prevent progression of tuberculosis infection to disease (see Chapter 6 of *Core Curriculum*).
- Provided that there is documentation of a tuberculin skin test classified as positive and that there has been a chest x-ray interpreted as negative following that tuberculin skin test, there is no need for further tuberculin testing. Similarly, there is no need for additional chest x-rays unless the person develops symptoms compatible with pulmonary tuberculosis.

Diagnostic Procedure: The Tuberculin Test
Follow-up with Diagnostic Service Program

POLICY: To provide tuberculosis evaluation services for those economically disadvantaged patients who have been identified as infected with or suspected of having tuberculosis.

PURPOSE: To control and eliminate tuberculosis through a comprehensive system of diagnostic evaluation, appropriate and effective treatment, consultation, technical assistance and education.

PROCEDURE: The patient is identified by the LPHA as being tuberculin skin test positive, not covered by health care insurance, and without financial capability of accessing diagnostic medical evaluation for tuberculosis. The eligibility of a client to participate in the Diagnostic Services Program is determined by the LPHA.

The patient chooses a physician from among the list of Diagnostic Services providers. The Section for Communicable Disease Prevention, Disease Investigation Unit mails updated listing of Diagnostic Services providers to LPHAs on a quarterly basis.

Prior to the LPHA making an appointment with a Diagnostic Services provider, the LPHA must request authorization from the Section for Communicable Disease Prevention, Disease Investigation Unit. A separate authorization request is required for each provider visit. The LPHA provides the following information to the Unit:

a) Patient's name,
b) Date of birth,
c) Social security number,
d) Telephone number,
e) Address,
f) Name of physician to whom the patient is referred.

The LPHA will generate a Diagnostic Services Eligibility/Authorization Form (MO 580-2615 (1-03)). The LPHA must then fax the form to the Disease Investigation Unit for authorization. (Verbal authorization will no longer be given). The LPHA should indicate the services requested for each patient. The Disease Investigation Unit will then authorize the services and fax the form back to the LPHA and to the provider.

The LPHA assures that an appointment is made for the patient and that appropriate follow-up takes place.

If medications are prescribed, the physician may personally call the contract pharmacy (see Section 4.4) or instruct the LPHA to call in the prescription. A copy of the prescription for the entire prescribed course of medications must be sent to the LPHA.
Patients are to receive medications and routine monitoring on a monthly basis by the LPHA.

All clinical specimens for diagnostic tests are to be sent to the State Tuberculosis Laboratory, so that there will be no costs incurred by either the participating physician or the patient (see Section 5.1).

All bills for tuberculosis services provided by the participating physicians are to be submitted to the Section of Communicable Disease Prevention, Disease Investigation Unit, **NOT** to the LPHA.